

REMARKS

Claims 1-18 remain in the application. Claims 1, 6, 8, 9, 14, 15, 17, and 18 have been amended. A version with markings to show changes made follows page 8. Reconsideration of this application, as amended, is respectfully requested.

Claim 1 has been amended to specify that the at least one optical property is measured at a first area and at a second area on a body part of the human subject to obtain a first set of data and a second set of data, respectively. Support for this amendment can be found at page 13, line 28 through page 14, line 2 of the specification. Claim 1 has been amended to specify that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part. Support for this amendment can be found at page 13, line 28 through page 14, line 2 of the specification.

Claim 8 has been amended to specify that the population comprises a first sub-population comprising a sufficient number of human subjects in the disease state and a second sub-population comprising a sufficient number of human subjects not in the disease state. Support for this amendment can be found at page 29, line 1 through page 34, line 7 of the specification.

Claim 15 has been amended to specify that the at least one optical property is measured at a first area and at a second area on a body part of the human subject to obtain a first set of data and a second set of data, respectively. Support for this amendment can be found at page 13, line 28 through page 14, line 2 of the specification. Claim 15 has been further amended to specify that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part. Support for this amendment can be found at page 13, line 28 through page 14, line 2 of the specification.

Claim 17 has been amended to specify that the apparatus comprises at least one source of light capable of illuminating at least two morphologically similar, adjacent, not substantially overlapping areas of a body part with light. Support for this amendment can be found at page 13, line 28 through page

14, line 2 of the specification. Claim 17 has been further amended to replace "means plus function" expressions with structural terminology. Support for these amendments can be found at page 14, line 9 through page 16, line 4 of the specification.

Claim 18 has been amended to replace the "means plus function" expression with structural terminology. Support for this amendment can be found at page 15, lines 22-26 of the specification.

Claims 9-18 were rejected under 35 U. S. C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been addressed by the amendments to claims 9 and 17.

Claims 1-4, 6-7, 9-12, 14, and 16-18 were rejected under 35 U. S. C. § 102 (b) as being anticipated by U. S. Patent 5,978,691 to Mills. This rejection is respectfully traversed for the following reasons.

Mills, U. S. Patent No. 5,978,691 (hereinafter "Mills"), discloses a method for facilitating the noninvasive determination of characteristics of subject matter and the environment in which said subject matter exists, the method comprising the steps of:

- Emitting at least one wavelength of electromagnetic radiation applied to
said subject matter
- Detecting said wavelength after contact with said subject matter
- Inducing a temperature change in said subject matter while emitting
and detecting said radiation applied to said subject matter
- Computing parameters based on information processed from the
contact of said radiation at various temperature levels on said
subject matter.

As shown in FIGS. 5b, 5c, 7, and 8 of Mills, the device and method employ multiple finger probes. In FIG. 5b, probe 26 is attached to one finger and probe 27 is attached to another finger. In FIG. 5c, probe 32 is attached to one finger, probe 34, is attached to a second finger, and probe 36 is attached to a third finger. FIGS. 7 and 8 illustrate multiple finger probes. Each individual finger constitutes a separate body part. In claims 1, 9, and 17, as amended, and the claims depending from claims 1, 9, and 17, (a) at least one optical property is measured at a first area on a

body part of the human subject to obtain a first set of data, the first area being subjected to a first temperature program; and (b) at least one optical property is measured at a second area on the body part of the human subject to obtain a second set of data, the second area being subjected to a second temperature program, the second temperature program being different from the first temperature program, the second area of the body part being morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part. Thus, in Mills, separate temperature programs are run on separate body parts, while in the claims of this application, separate temperature programs are run on the same body part, but the areas on the body part must be morphologically similar, adjacent, but not substantially overlapping. Thus, it is clear that Mills does not anticipate claims 1-4, 6-7, 9-12, 14, and 16-18, as amended, or any other claim of this application.

Claims 5, 8, 13, and 15 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over U. S. Patent 5,978,691 to Mills. This rejection is respectfully traversed for the following reasons.

Claim 8 has been amended to specify that the population comprises a first sub-population comprising a sufficient number of human subjects in the disease state and a second sub-population comprising a sufficient number of human subjects not in the disease state. Mills does not disclose or suggest the division of the population of human subjects into two sub-populations. Furthermore, Mills does not disclose or suggest that the at least one optical property is measured at a first area and at a second area on a body part of the human subject to obtain a first set of data and a second set of data, respectively, and that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part.

Claim 15 has been amended to specify that the at least one optical property is measured at a first area and at a second area on a body part of the human subject to obtain a first set of data and a second set of data, respectively, and that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part. Mills does not disclose or suggest that the at least one optical property is measured at a first area and at a second area on a body part of a human subject to obtain a first set of data and a second set of data,

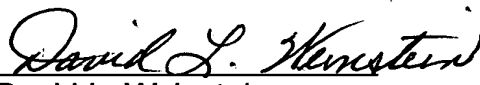
respectively, and that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part.

Claims 5 and 13 merely relate to the sequence of measuring steps (a) and (b). While Mills discloses the sequence of steps set forth in claims 5 and 13, Mills fails to disclose or suggest that the at least one optical property is measured at a first area and at a second area on a body part of the human subject to obtain a first set of data and a second set of data, respectively, and that the second area of the body part is morphologically similar to, adjacent to, but not substantially overlapping with the first area of the body part. In view of the amendments to claims 1, 8, 9, and 15, it is submitted that Mills does not render claims 5, 8, 13, and 15, or any other claim of this application, obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1-18, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Kindly rewrite claims 1, 6, 8, 9, 14, 15, 17, and 18 as follows:

1. (Once amended) A method for the determination of a disease state in [a tissue of] a human subject, said method comprising the steps of:
 - (a) measuring at least one optical property at a first area on [said tissue] a body part of said human subject to obtain a first set of data, said first area being subjected to a first temperature program;
 - (b) measuring at least one optical property at a second area on said [tissue] body part to obtain a second set of data, said second area being subjected to a second temperature program, said second temperature program being different from the first temperature program, said second area of said body part being morphologically similar to , adjacent to, but not substantially overlapping with said first area of said body part; [and]
 - (c) inserting said first set of data and said second set of data into a mathematical relationship to calculate a mathematical output; and
 - (d) comparing said mathematical output to a category selector to determine said disease state of said human subject.

8. (Once amended) The method of claim 1, wherein said mathematical relationship of step (c) is derived by a method comprising the steps of:
 - (a) providing a population comprising a sufficient number of human subjects to establish a category selector , said population comprising a first sub-population comprising a sufficient number of human subjects in said disease state and a second sub-population comprising a sufficient number of human subjects not in said disease state;
 - (b) for each of said number of human subjects in said population:
 - (1) measuring at least one optical property at a first area on [said tissue] a body part of said human subjects to obtain a first set of data, said first area being subjected to a first temperature program;

- (2) measuring at least one optical property at a second area on said [tissue] body part of said human subjects to obtain a second set of data, said second area being subjected to a second temperature program, said second temperature program being different from the first temperature program, said second area of said body part being morphologically similar to , adjacent to, but not substantially overlapping with said first area of said body part; and
- (c) establishing a mathematical relationship between (i) said optical properties of said first set of data and said second set of data and (ii) said disease state.

9. (Once amended) A method for determining [the] concentration of an analyte in [human tissue] a body part, said method comprising the steps of:

- (a) measuring at least one optical property at a first area on said [tissue] body part to obtain a first set of data, said first area being subjected to a first temperature program;
- (b) measuring at least one optical property at a second area on said [tissue] body part to obtain a second set of data, said second area being subjected to a second temperature program, said second temperature program being different from the first temperature program, said second area of said body part being morphologically similar to said first area of said body part, said second area of said body part [but] not substantially overlapping with said first area of said body part, and said second area of said body part being adjacent to said first area of said body part; and
- (c) inserting said first set of data and said second set of data into a mathematical relationship to calculate said concentration of said analyte.

15. (Once amended) The method of claim 9, wherein said mathematical relationship of step (c) is derived by a method comprising the steps of:

- (a) providing a population comprising a sufficient number of human subjects to establish a statistically meaningful mathematical relationship;

(b) for each of said number of human subjects in said population:

(1) measuring at least one optical property at a first area on [said tissue] said body part to obtain a first set of data, said first area being subjected to a first temperature program;

(2) measuring at least one optical property at a second area on said [tissue] body part to obtain a second set of data, said second area of said body part being subjected to a second temperature program, said second temperature program being different from the first temperature program, said second area of said body part being morphologically similar to said first area of said body part, said second area of said body part [but] not substantially overlapping with said first area of said body part, and said second area of said body part being adjacent to said first area of said body part; and

(c) establishing a mathematical relationship between (i) said optical properties of said first set of data and said second set of data and (ii) said concentration of analyte.

17. (Once amended) An apparatus for determining a disease state of a human subject or [the] concentration of an analyte in [the tissue] a body part of a human subject, said apparatus comprising:

(a) [means for] at least one source of light capable of illuminating at least two morphologically similar, adjacent, not substantially overlapping areas of [tissue] said body part with light;

(b) [means for] at least one light collecting element to collect [collecting] light re-emitted from said at least two areas of [tissue] said body part;

(c) [means for] a detector for measuring the intensity of said re-emitted light collected at said two areas of [tissue] said body part; and

(d) [means for] a controller for controlling the temperature of said at least two areas of said [tissue] body part simultaneously by means of temperature programs.

18. (Once amended) The apparatus of claim 17, further including (e) [means for] a computer for correlating the intensity of the re-emitted light collected at

said at least two areas of said [tissue] body part with said concentration of an analyte or said disease state, provided that said at least two areas of said body part are morphologically similar , adjacent, and [are] substantially non-overlapping.